UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SHELLER, P.C.,	:	**CIVIL ACTION**
	:	
Plaintiff,	:	
	:	
v.	:	
	:	
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*.,	:	
	:	
Defendants.	:	**NO. 15-CV-440**

ORDER

AND NOW, this day of , 2015, upon consideration of the federal defendants' motion to dismiss for lack of subject-matter jurisdiction (Dkt. Entry No. 10), and plaintiff's opposition thereto, it is hereby ORDERED that:

1. The motion is GRANTED pursuant to Federal Rule of Civil Procedure 12(b)(1).

2. The Court hereby DISMISSES all of plaintiff's claims against the federal defendants, who are the only defendants in this case.

BY THE COURT:

_____
HONORABLE LEGROME D. DAVIS
United States District Court Judge

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	:	
Defendants.	:	**NO. 15-CV-440**

FEDERAL DEFENDANTS' MOTION TO DISMISS

Pursuant to Federal Rule of Civil Procedure 12(b)(1), and for the reasons more fully stated in the accompanying brief, the federal defendants (the only defendants in this action) respectfully move to dismiss all of the claims in this action, for lack of plaintiff's constitutional standing to bring them, all as proposed in the accompanying order.

Respectfully submitted,

ZANE DAVID MEMEGER
United States Attorney

/s/ Joan K. Garner, for
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Assistant United States Attorney
Chief, Civil Division

/s/ Gerald B. Sullivan GBS3408
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Plaintiff,	:	
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Defendants.	:	**NO. 15-CV-440**

BRIEF SUPPORTING FEDERAL DEFENDANTS' MOTION TO DISMISS

Plaintiff Sheller, P.C. ("Sheller"), a law firm, purports to represent "hundreds of children" in personal injury litigation against Johnson & Johnson and its subsidiary Janssen Pharmaceuticals (hereinafter "J&J"), concerning two antipsychotic drugs, Risperdal (risperidone) and Invega (paliperidone). See Complaint, Dkt. Entry No. 1, ¶ 1. Despite broad averments in this case about facts and issues raised in that litigation, Sheller fails to allege any injury satisfying the "injury-in-fact" requirement for Article III (constitutional) standing on the pleaded claims against the federal defendants here, who are not parties to the private J&J litigation.[1] See Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992) (recognizing this requirement).

Constitutional standing is wanting because Sheller alleges merely and insufficiently that the FDA's denial of the Sheller firm's citizen petition was arbitrary and capricious and thereby procedurally injured Sheller, and not further -- as Article III demands -- that Sheller suffered substantive, cognizable injury from that petition denial.

[1] The "federal defendants," who are all of the defendants in this action, are: (1) the United States Department of Health and Human Services ("HHS"); (2) the U.S. Food and Drug Administration ("FDA"); (3) the HHS Secretary, Sylvia Matthews Burwell; and (4) the FDA Commissioner, Margaret A. Hamburg, M.D.

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This absence of plausible allegations of constitutional standing is apparent when the petitioned-for relief is compared to Sheller's allegations in this action, as follows:

- The citizen petition requested FDA to revoke the pediatric (i.e., use in children) indication for Risperdal and Invega, and to require a new warning on the labeling for Risperdal and all generic risperidone products. But here, Sheller does not allege that it is or was a user of those drugs or suffered adverse events from them. And
- The citizen petition requested FDA to "direct" J&J to release Sheller from protective orders and confidentiality agreements (which Sheller and J&J voluntarily entered into during their private litigation) because these supposedly prevented Sheller from providing FDA with confidential documents supportive of Sheller's citizen petition. But here, Sheller has not alleged that it did not voluntarily enter into those agreements, let alone that the FDA: (a) was a party to those agreements; (b) caused Sheller to enter into them; or (c) has any authority to release Sheller from them.

See Complaint, ¶¶ 9, 21, 22; see also Letter from J. Woodcock to S. Sheller and C. Gomez (Nov. 25, 2014) ("FDA Response"), attached to Complaint as Exhibit "H" and hereto as Exhibit "A."

Because Sheller fails to allege an injury that it sustained as a result of the FDA's denial of its citizen petition -- let alone an injury that can be redressed in this case – this Court must dismiss this case under Federal Rule 12(b)(1) for lack of subject-matter jurisdiction. See, e.g., Hydro Investors, Inc. v. FERC, 351 F.3d 1192, 1197 (D.C. Cir. 2003) ("If the petitioner has no Article III concrete interest in receiving the relief requested before the agency . . . Congress has no power to grant a petitioner a right to seek judicial review of an agency's decision to deny him relief").

BACKGROUND

I. Statutory and Regulatory Background

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), pharmaceutical companies seeking to market new drug products must first obtain FDA approval by filing a new drug application ("NDA") or abbreviated new drug application ("ANDA"). 21 U.S.C. § 355. Before approving an NDA, FDA must first determine that the drug is safe and effective for use under the conditions prescribed, recommended, or suggested in the product's labeling. 21 U.S.C. §§ 355(b)(1), (d). If safety concerns arise after an approved drug enters the marketplace, FDA may take regulatory action if warranted and appropriate, including withdrawing a drug product's approval, see 21 U.S.C. § 355(e)(1)-(2), or requiring inclusion of new safety information in the product's labeling. See 21 U.S.C. § 355(o)(4).

An FDA regulation, 21 C.F.R. § 10.30, permits any interested party to file with the FDA a citizen petition asking the agency to take (or refrain from taking) an action. The regulation also outlines the relevant procedure for FDA's response to citizen petitions, and notes that the FDA Commissioner "may" hold conferences, meetings, and/or hearings in reviewing a petition. 21 C.F.R.§ 10.30(h).

II. Factual Background

Sheller submitted a citizen petition to FDA on July 27, 2012, and an amendment to that petition on August 27, 2012. See FDA Response, Exhibit "A" hereto, at 1. These requested FDA to: (1) revoke the pediatric indication for Risperdal and Invega; (2) require a new warning on the labeling of Risperdal and Invega regarding the "lack of sufficient safety data" on the risk of gynecomastia (breast enlargement in males caused by elevated levels of prolactin, a hormone produced by the pituitary gland); and (3) "direct" J&J to permit Sheller to provide protected,

confidential J&J documents to FDA. Id. at 1-2, 7. By letter dated November 25, 2014, FDA granted one aspect of one of these requests, and denied the remainder of the petition. Id. Sheller's contentions, and the FDA's responses, were as follows.

Sheller claimed that its first two requests were supported by the absence of long-term safety data for Risperdal and Invega, as well as the incidence of adverse events associated with the two drugs. See FDA Response, at 1, 3. In response, FDA first explained that "based on reviews of clinical data submitted by the sponsor, published literature, and postmarketing surveillance, there is no evidence that [Risperdal or Invega] is unsafe, and no evidence that [Risperdal or Invega] is not shown to be safe, for use under the conditions of use upon the basis of which the applications were approved that would warrant revocation of the pediatric indication of these drugs." Id. at 4. FDA continued: "the lack of quality, long-term clinical safety information . . . is not an appropriate reason to revoke the pediatric indications of Risperdal and Invega when weighed against the potential therapeutic benefit derived from the use of these drugs." Id. at 5.

In response to Sheller's labeling request, FDA noted that the relevant FDA guidance document provides for the use of boxed warnings when: (1) an adverse reaction is so serious in proportion to the potential benefit from the drug (for example, it is life-threatening or permanently disabling) that it must be considered in assessing the risks and benefits of the drug; (2) a serious adverse reaction can be prevented or reduced in severity by appropriate use of the drug; or (3) the drug was approved with restrictions because the drug can be safely used only if distribution or use is restricted. Id. at 6. Because none of these situations is applicable to Risperdal or Invega, and because "[t]he risks of treatment with these drug products, including the

risks with which your [Sheller] petition is principally concerned, are well known," FDA denied Sheller's request to add a boxed warning to the labeling of Risperdal and Invega. Id. at 6-7.

Sheller's petition further requested FDA to "direct J&J to release [Sheller] from 'any and all standing Confidentiality/Protective Orders' so that [Sheller] can present to the FDA the 'internal documents and data,' as well as an expert analysis thereof," which Sheller claimed supported its petition requests. See FDA Response, at 8. In the alternative, Sheller requested that FDA ask J&J for all internal documents, as well as testimony, from the litigation between Sheller and J&J. Id. at 8-9. In response, FDA asked J&J to provide the agency with "any data in its possession relevant to the use of risperidone or paliperidone in children and adolescents that J&J has not previously provided to the Agency." Id. at 9. J&J then provided certain information to FDA in response to this request, which FDA considered along with all other relevant information in addressing Sheller's citizen petition. Id. Thus, FDA granted in part and denied in part Sheller's third request.

ARGUMENT

I. Standard of Review

"A federal court must dismiss a complaint for lack of subject matter jurisdiction under the case-or-controversy requirement of Article III of the United States Constitution if the plaintiff lacks standing to bring a claim." Travelers Indem. Co. v. Cephalon, Inc., 32 F. Supp. 3d 538, 544 (E.D. Pa. 2014) (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992)). The standing requirement seeks to ensure that the plaintiff has "'alleged such a personal stake in the outcome of the controversy' as to warrant his invocation of federal-court jurisdiction and to justify exercise of the court's remedial powers on his behalf." Warth v. Seldin, 422 U.S. 490, 498-99 (1975) (quoting Baker v. Carr, 369 U.S. 186, 204 (1962)).

A motion to dismiss for lack of standing is brought under Federal Rule of Civil Procedure 12(b)(1). In re: Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 243 (3d Cir. 2012). On a Rule 12(b)(1) facial attack on plaintiff's standing, as here, the Court applies Rule 12(b)(6) standards in reviewing the sufficiency of the complaint and its attached and referenced documents. Id. The plaintiff must allege "facts that affirmatively and plausibly suggest that the pleader has . . . the right to jurisdiction" and that go beyond "facts that are merely consistent with such a right." Id. at 243-44 (citation and quotation marks omitted); accord Canale v. Allstate Property and Casualty Ins. Co., 2013 WL 10002133, at *3 (E.D. Pa. Nov. 21, 2013) (Davis, J.); see also Allison v. Aetna, Inc., 2010 WL 3719243, at *2 (E.D. Pa. Mar. 9, 2010) (Davis, J.) (noting that "A federal court is powerless to create its own jurisdiction by embellishing otherwise deficient allegations of standing") (quotation marks and citations omitted).

Plaintiff Sheller bears the burden of plausibly alleging (and ultimately establishing) the three elements of Article III standing: (1) "injury in fact"; (2) "a causal connection between the injury and the conduct complained of"; and (3) likelihood that a favorable decision will redress the injury. Defenders of Wildlife, 504 U.S. at 560-61, cited in In re: Schering Plough Corp., 678 F.3d at 244. The first element, injury-in-fact, is often determinative, and must be both "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." Defenders of Wildlife, 504 U.S. at 560 (quotations omitted), 563 (this "requires more than an injury to a cognizable interest. It requires that the party seeking review be himself among the injured").[2]

[2] See also Toll Bros., Inc. v. Township of Readington, 555 F.3d 131, 138 (3d Cir. 2009) ("The injury can be widely shared, but it must nonetheless be concrete enough to distinguish the interest of the plaintiff from the generalized and undifferentiated interest every citizen has in good government. In this way, injury-in-fact "keeps the judicial branch from encroaching on

II. Sheller Lacks Constitutional Standing

Sheller's claimed injury is rooted in allegations that: (1) FDA's denial of its citizen petition was arbitrary and capricious, Complaint ¶ 39; (2) as a result of that denial, Sheller is unable to disclose confidential documents, which impedes its ability to represent its clients effectively, id. ¶¶ 40-41; and (3) the consumers Sheller represents continue to be harmed by effects of taking Risperdal and/or Invega. Id. ¶¶ 15, 47, 53.

As discussed below, none of these allegations, even if accepted as true for purposes of this motion, provides Sheller with standing to pursue this case.

A. FDA's denial of Sheller's citizen petition does not give Sheller standing

Sheller illogically claims that FDA's denial of its citizen petition deprives Sheller of the right to file a citizen petition. Complaint, ¶ 39. This assertion is belied by Sheller's filing a citizen petition that FDA considered and substantively answered. More importantly, FDA's denial of the petition, without more, does not constitute the injury-in-fact necessary for Article III standing.

It is well-settled that participation in an agency's administrative proceeding does not confer Article III standing to seek substantive federal court review of the agency's decision. See, e.g., Klamath Water Users Ass'n v. Fed. Energy Regulatory Comm'n, 534 F.3d 735, 738 (D.C. Cir. 2008) ("[p]etitioners do not have a right to seek court review of administrative proceedings

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legislative prerogatives, thereby preserving the separation of powers.") (internal citations and quotations omitted); accord Comité de Apoyo a Los Trabajadores Agricolas v. Perez, 2014 WL 3629528, at *7 (E.D. Pa. July 23, 2014) (Davis, J.) (citing this language from the Toll Bros. decision and stating, "Plaintiffs do not have standing to sue for broad, programmatic changes untethered to a concrete case or controversy").

merely because they participated in them") (quotation omitted).[3] As the D.C. Circuit has explained, agencies -- unlike the federal courts -- "are not constrained by Article III." Fund Democracy, LLC v. SEC, 278 F.3d 21, 27 (D.C. Cir. 2002) (citations omitted). Agencies may therefore "permit persons to intervene in the agency proceedings who would not have standing to seek judicial review of the agency action." Id. (rejecting argument that individual's status as an "interested person" in administrative proceeding was sufficient to confer standing to petition district court for review of an SEC order).[4]

As a constitutional requirement, Sheller must here therefore establish not merely petitioner status but injury resulting from the FDA's decisions not to: (1) revoke the pediatric indication for Risperdal and Invega; (2) require the requested labeling change; and (3) require J&J to release Sheller from confidentiality agreements. The Eighth Circuit recognized this in

[3] Accord, e.g., KERM, Inc. v. FCC, 353 F.3d 57, 59 (D.C. Cir. 2004) ("That a petitioner participated in administrative proceedings before an agency does not establish that the petitioner has constitutional standing to challenge those proceedings in federal court"); Fund Democracy, LLC v. SEC, 278 F.3d 21, 27 (D.C. Cir. 2002) (holding that SEC rule allowing an "interested person" to request an administrative hearing did not confer Article III standing, because "[p]articipation in agency proceedings is alone insufficient to satisfy judicial standing requirements"); Inner City Press v. Bd. of Governors, 130 F.3d 1088, 1089 (D.C. Cir. 1997) ("[P]articipation in administrative proceedings before the Board of Governors of the Federal Reserve System, like such participation before any agency . . . does not, without more, satisfy a petitioner's Article III injury-in-fact requirement") (citation omitted); Overton Power Dist. No. 5 v. O'Leary, 73 F.3d 253, 257 (9th Cir. 1996) ("[I]t does not necessarily follow that a party able to participate in administrative proceedings therefore has standing to challenge agency decisions."); Am. Legal Found. v. FCC, 808 F.2d 84, 89 (D.C. Cir. 1987) (holding that plaintiff could not "claim standing solely by virtue of its participation in proceedings before the Commission").

[4] Accord, e.g., Hydro Investors, Inc. v. FERC, 351 F.3d 1192, 1197 (D.C. Cir. 2003) ("If the petitioner has no Article III concrete interest in receiving the relief requested before the agency. . . Congress has no power to grant a petitioner a right to seek judicial review of an agency's decision to deny him relief"); Gettman v. DEA, 290 F.3d 430, 433 (D.C. Cir. 2002) ("Petitioners may be 'interested parties' under the statute, and therefore able to petition the agency, and yet not have Article III standing to bring [an] action in federal court.").

holding that a government contractor lacked Article III standing to seek judicial review of the FAA's award of a contract to a different contractor. Wilcox Elec., Inc. v. FAA, 119 F.3d 724, 727-28 (8th Cir. 1997). The court emphasized that the claimed injury from denial of plaintiff's administrative protest of the award did not suffice; rather, the plaintiff had to show injury resulting from FAA's decision to award the contract to the other contractor. Id. (reasoning that to "allow the losers in such disputes to appeal to the federal courts, asserting that loss as their injury in fact, would be to grant such parties Article III standing merely because Congress granted them standing to appear in the agency adjudication," a result that "would, in essence, improperly allow Congress to modify the constitutional requirements of standing"); accord, e.g., Hydro Investors, Inc. v. FERC, 351 F.3d 1192, 1197 (D.C. Cir. 2003) ("Any other rule would allow Congress to create federal jurisdiction by the simple expedient of granting any party – no matter how far removed from the true controversy – a right to petition the agency, and then a right to seek judicial review if the agency denied the request. Article III does not permit Congress to expand the federal judicial function through such stratagems.").

These Article III requirements are not altered or eliminated by an FDA regulation, 21 C.F.R. § 10.45(d)(1)(ii), providing that an "interested person" who files a citizen petition has standing to obtain judicial review of final agency action regarding that petition. See Olamide Olorunniyo Ore v. Clinton, 675 F. Supp. 2d 217, 223 (D. Mass. 2009) ("Whether a litigant has standing to sue in federal court . . . is not dependent on any agency regulation."); cf. Rivas v. Rail Delivery Serv., Inc., 423 F.3d 1079, 1083 (9th Cir. 2005) ("A federal statute . . . cannot confer standing on plaintiffs who do not meet Article III requirements."). Article III standing is more demanding than FDA's regulations, which authorize any person to submit a citizen petition, see 21 C.F.R. § 10.30(a), and broadly define an "interested person" as "a person who

submits a petition or comment or objection or otherwise asks to participate in an informal or formal administrative proceeding or court action," 21 C.F.R. § 10.3(a). To allow an agency to confer judicial standing upon an entire class of "interested persons" who choose to participate in its proceedings would circumvent Article III's standing requirements. As the D.C. Circuit has recognized, the difference between the "interest" allowing a party to petition an agency at the will of Congress, and the "interest" required for standing in the courts, is "fundamentally the difference between the political branches on the one hand and the Article III courts on the other." Gettman v. DEA, 290 F.3d 430, 433 (D.C. Cir. 2002)

Sheller thus cannot overcome the bedrock principle that an agency regulation cannot confer constitutional standing, as one district court in this Circuit (in agreeing with FDA) recognized in the only reported decision to address Article III vis-à-vis the subsection 10.45(d)(1)(ii) FDA "interested person" citizen petition regulation. In Schering Corp. v. FDA, 866 F. Supp. 821 (D.N.J. 1994), the plaintiff argued that subsection 10.45(d)(1)(ii) conferred Article III standing because the plaintiff had participated in the rulemaking process for the regulations at issue in that case and was therefore an "interested person." Id. at 824. The court, however, "agree[d] with the FDA's [contrary] arguments that an administrative agency cannot circumvent the requirements for Article III standing" through a regulation. Id, aff'd, 51 F.3d 390, 394 n. 6 (3d Cir. 1995) (Third Circuit: (1) noting that the district court so found; and (2) not stating any disagreement).[5]

[5] In 2012 decisions granting FDA's motion to dismiss and which the Ninth Circuit affirmed, the Central District of California district court held that an organization could not show standing based solely on FDA's denial of its citizen petition. See: (1) Physicians for Integrity in Medical Research, Inc. v. Commissioner, Civil Case 11-08334 GAF, slip op. at 4 (C.D. Ca. Mar. 16, 2012) ("Standing must be established independent of the Agency's administrative denial"), attached hereto as Exhibit "B"; (2) Physicians for Integrity (same case), "Order" (C.D. Cal. May

Therefore, because Sheller has not plausibly alleged injury apart from either mere FDA denial of its citizen petition -- or status as an "interested person" entitled to participate in the FDA citizen petition proceeding under the FDA's regulation -- the law firm lacks Article III standing, and its claims must be dismissed for lack of jurisdiction.

B. The 3d-party agreements do not establish standing against the government

Sheller's next attempt to establish an injury-in-fact stems from its apparent frustration with being bound by private protective and/or confidentiality agreements with J&J. Sheller alleges, in conclusory fashion, that "its inability to disclose the Confidential Documents" interferes with its ability to represent its clients in the personal injury litigation(s), increases the costs to Sheller in the personal injury litigation(s), and prevents Sheller from acting "on the information it has to protect its clients' safety." Complaint, ¶¶ 40, 41. But Sheller fails to allege how being held to the terms of the confidentiality agreements that it chose to enter into during the course of litigation with J&J constitutes an injury.

Moreover, even if this Court were to conclude that being bound to a confidentiality agreement constitutes an injury-in-fact, Sheller cannot show that this "injury" is traceable to FDA or redressable by the relief requested. See, e.g., Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992) (one "irreducible constitutional minimum" of Article III standing is that "the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court"); AT&T Communications of N.J., Inc. v. Verizon N.J., Inc., 270 F.3d 162, 171 (3d Cir. 2001) ("Even if we were to determine that the Advocate suffered an injury-in-fact, we would still conclude that the Advocate lacks standing

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23, 2012), attached hereto as Exhibit "C"; and (3) Physicians for Integrity in Medical Research, Inc. v. Hamburg, 556 Fed. Appx. 621 (9th Cir. Feb. 24, 2014) (affirming district court).

because its alleged injury is not redressable."). FDA is not a party to any of the confidentiality agreements between Sheller and J&J, and it is therefore impossible for FDA to have caused Sheller's inability to disclose the confidential documents in question. In addition, FDA does not have the authority to release Sheller from confidentiality agreements to which FDA is not a party, and Sheller's complaint is tellingly silent on the purported source of any such FDA authority. A court order that FDA "direct J&J and Janssen to consent to release Sheller from any confidentiality/protective orders," as requested in Paragraph B.a of the Complaint, would have no impact on Sheller's purported injury unless J&J (not a party to this action) voluntarily decided to release Sheller from the relevant confidentiality and/or protective orders. There is no indication that J&J would do so.

Similarly, Sheller's alternative requested relief (Complaint, ¶ B.b.) -- that J&J "submit directly to the FDA any documents relating to [Risperdal and Invega] that it has not previously submitted to the FDA," and that such documents then be made public -- is predicated on non-party J&J agreeing to the release of such documents. Once again, Sheller's requested relief is not within FDA's control. Indeed, the Complaint itself acknowledges that the confidential documents in question "are in J&J's possession and control," Complaint ¶ 95, and further suggests that even if this Court were to conclude that Sheller alleged an injury-in-fact regarding its ability to provide FDA with certain documents, such injury is not redressable in a lawsuit against FDA.

C. Alleged harm to Sheller's clients does not provide Sheller with standing

Sheller appears to assume that the purported injuries suffered by the children it represents in the personal injury litigation against J&J suffice as injuries to Sheller for purposes of this case. See, e.g., Complaint, ¶ 15 ("FDA's decision puts at risk numerous pediatric patients who are

prescribed [Risperdal and Invega]"), ¶ 47 ("the Risperdal Drugs cause serious adverse events"), ¶ 53 ("the adolescent, teen, and pre-teen boys whom Sheller represents and who have developed breasts as a result of the ingestion of the Risperdal Drugs uniformly report being bullied . . . and ostracized by their peers.").[6] But "'[i]t is the fact, clearly established, of injury to the complainant—not to others—which justifies judicial intervention.'" Hayes v. Wal-Mart Stores, Inc., 725 F.3d 349, 360-61 (3d Cir. 2013) (quoting McCabe v. Atchison, Topeka, & Santa Fe Ry. Co., 235 U.S. 151, 162 (1914)); see also Montone v. City of Jersey City, 709 F.3d 181, 196 (3d Cir. 2013) ("when the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily substantially more difficult to establish.") (internal citation and quotation omitted).

Because Sheller has not alleged that any member of Sheller, P.C. took Risperdal or Invega or suffered any of the adverse events cited in the Complaint, the alleged adverse effects from the use of Risperdal or Invega do not constitute a constitutionally sufficient injury-in-fact to Sheller.

[6] Sheller also alleges that the "current prescribing information for the Risperdal Drugs actively impedes physicians' ability to comply with the standard of care for the monitoring, diagnosis and treatment of hyperprolactinemia." Complaint, ¶ 59; see also id. ¶¶ 60, 63, 65, 66, 72 (alleging similar regarding impediments to physicians' standard of care). But Sheller has not alleged that it has any physicians on its staff, much less one who prescribes Risperdal and/or Invega for this condition. Any purported injury suffered by physicians in general thus does not serve as injury-in-fact to support standing for Sheller.

CONCLUSION

For the foregoing reasons, the federal defendants respectfully request the Court to dismiss plaintiff Sheller's Complaint pursuant to Rule 12(b)(1) for lack of subject-matter jurisdiction.

Respectfully submitted,

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United States Attorney

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Dated: April 3, 2015

CERTIFICATE OF SERVICE

I hereby certify that today, April 3, 2015, I served a true and correct copy of the foregoing Federal Defendants' Motion to Dismiss, with accompanying brief, by First-class mail, postage prepaid, upon:

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The motion and brief have been filed electronically and are available for viewing and downloading from the Court's Electronic Case Filing ("ECF") System. In addition to mail service, these documents have been electronically served today on the above-named counsel, who have consented to electronic service. Such service has been made at the above email addresses, which are listed on the Docket Sheet in this case.

/s/ Gerald B. Sullivan GBS3408
Gerald B. Sullivan
Assistant United States Attorney

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DEPARTMENT OF HEALTH & HUMAN SERVICES

NOV 25 2014

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

Stephen A. Sheller, Esq.
Christopher A. Gomez, Esq.
Sheller, P.C.
1528 Walnut Street, 4th Floor
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Re: Docket No. FDA-2012-P-0857

Dear Mr. Sheller and Mr. Gomez:

This responds to your citizen petition received on July 27, 2012, and amended on August 27, 2012.[1] Your petition, as amended,[2] requests that the Food and Drug Administration (FDA or Agency) revoke the pediatric indication for Risperdal (risperidone), for all generic versions of risperidone, and for Invega (paliperidone), unless and until the long-term safety of these drug products can be demonstrated. Alternatively, you request that FDA require a new boxed warning for Risperdal and all generic versions of risperidone that would warn of what you characterize as a lack of sufficient safety data. Finally, you also ask that FDA direct Johnson & Johnson, Inc. (J&J) to consent to release you from any and all standing Confidentiality/Protective Orders so that you can present to the Agency "internal documents and data, as well as an expert analysis thereof," which you believe support your requests (Petition at 2).

We have carefully considered your petition and the comments submitted to the docket. For the reasons described below, your requests are granted in part and denied in part.

I. BACKGROUND

A. Risperdal and Invega

Risperidone and its active metabolite, paliperidone, are antipsychotic drugs marketed in

[1] We also acknowledge your March 26, 2013, letter to FDA requesting that the Commissioner of Food and Drugs schedule a hearing to discuss your petition. In addition, we acknowledge your July 2, 2013, letter reiterating certain requests contained in your petition. We responded to these letters and posted both the letters and our responses to the docket associated with your petition.

[2] Your August 27, 2012, submission, which you characterize as an "amendment" to your August 2, 2012, petition, appears to be a replacement of your original petition. It contains some additional discussion in support of your requests but is otherwise identical to the original. Accordingly, we refer to your August 27, 2012, submission as the "Petition" or "your petition" throughout this response, and do not further refer to your original August 2, 2012, submission.

the United States as Risperdal and Invega, respectively. Risperdal (risperidone) is the subject of new drug application NDA 20-272 and was approved on December 29, 1993. It was indicated for the management of the manifestations of psychotic disorders. An additional indication for treatment of irritability associated with autistic disorder in children and adolescents was added in 2006. In 2007, the indications for schizophrenia and bipolar I disorder were expanded to include adolescents aged 13-17 and children and adolescents aged 10-17, respectively.

Invega (paliperidone) Extended-Release Tablets was approved on December 19, 2006. It is the subject of NDA 21-999. It was indicated for the treatment of schizophrenia. It is designed to deliver paliperidone — the active ingredient derived from risperidone.

Both drugs are known to elevate blood levels of prolactin, a naturally occurring hormone produced by the pituitary gland in the brain. Elevated levels of prolactin (hyperprolactinemia) from any cause can be associated with a number of clinical effects, including breast enlargement (also called gynecomastia).

Both Risperdal and Invega have been studied in adequate and well-controlled clinical trials in pediatric patients. As noted above, supplemental new drug applications (sNDAs) for the use of Risperdal in the treatment of irritability associated with autistic disorder in children and adolescents (ages 5-16 years), treatment of schizophrenia in adolescents (ages 13-17 years), and treatment of bipolar disorder in children and adolescents (ages 10-17 years) were approved on October 6, 2006; August 22, 2007; and August 22, 2007, respectively. An sNDA for the use of Invega in the treatment of schizophrenia in adolescents (ages 12-17 years) was approved on April 6, 2011.

B. Regulatory Framework

FDA's regulation of drug safety is governed by the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 et. seq.) and the Agency's implementing regulations (codified in Title 21 of the Code of Federal Regulations). The FD&C Act makes it unlawful to market a new drug product without first obtaining an approved NDA or abbreviated new drug application (ANDA).[3] Before approving an NDA, FDA must determine that the drug is both safe and effective for use under the conditions prescribed, recommended, or suggested in the product's labeling.[4]

After an approved drug enters the marketplace, FDA may have cause to reassess its safety and take regulatory action if warranted and appropriate. One possible action is withdrawal of a drug product's approval. Section 505(e)(1)-(2) of the FD&C Act provides that FDA shall withdraw approval of a drug product if the agency finds, after notice and opportunity for a hearing, that "clinical or other experience, tests, or other

[3] See section 505(a) of the FD&C Act (21 U.S.C. 355(a)); see also section 301(d) of the FD&C Act (21 U.S.C. 331(d)) (prohibiting the marketing of any article in violation of section 505).

[4] Section 505(b)(1) of the FD&C Act; section 505(d) of the FD&C Act.

scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved," or that:

> . . . new evidence of clinical experience, not contained in [the] application or not available to the Secretary until after [the] application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when [the] application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved.

Another possible regulatory action would be to require the inclusion of new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions, in product labeling (see section 505(o)(4) of the FD&C Act).

II. DISCUSSION

A. Request to Revoke Pediatric Indication or Require a Black Box Warning[5]

You request that the FDA revoke the pediatric indication for Risperdal (including all generic versions of risperidone) and Invega unless and until the long-term safety of these drug products can be demonstrated. Alternatively, you request that FDA require a boxed warning for Risperdal and all generic versions of risperidone (Petition at 1, 2).

You base your requests on the incidence of adverse events associated with Risperdal and Invega, including hyperprolactinemia and gynecomastia. You assert that the current labeling of these products fails to adequately inform and guide prescribers and contend that, as a result, patients who might otherwise be provided with alternative treatments are led to suffer adverse effects associated with Risperdal. As grounds for your request to revoke the pediatric indication or require a black box warning, you cite a lack of long-term safety data for these drug products.

For the reasons discussed below, we disagree with your assertion that what you characterize as a lack of long-term safety data is a basis for either revoking the pediatric indications for Risperdal or Invega or adding a new boxed warning to the labeling of these drug products.

1. Safety Information Supported Approval of Pediatric Indications; Subsequent Review Does Not Alter Our Conclusion

Before the approval of each pediatric indication for Risperdal and Invega, the Agency

[5] You note that your requests and the grounds for your requests apply to Risperdal (including generic versions of Risperdal) and Invega, though you do not specifically request a boxed warning for Invega (Petition at 1).

determined that sufficient short-term and long-term safety information to support approval had been presented by the drug sponsor.

Since the pediatric approvals were granted, we have: (1) examined required Annual Report submissions for any new safety signals related to Risperdal and Invega; (2) routinely monitored Agency data, including our adverse event reporting systems, for new safety signals; (3) asked for and received from the drug sponsor any data in their possession relevant to the use of Risperdal or Invega in children or adolescents that had not previously been submitted; and (4) conducted a thorough review of published literature[6] to identify any new safety concerns, including any concerns related to the long-term use of these drug products.

In sum, based on reviews of clinical data submitted by the sponsor, published literature, and postmarketing surveillance, there is no evidence that the drug is unsafe, and no evidence that the drug is not shown to be safe, for use under the conditions of use upon the basis of which the applications were approved that would warrant revocation of the pediatric indication of these drugs.

2. *The Absence of Additional Long-Term Safety Data Does Not Support Revoking the Pediatric Indications for Risperdal and Invega*

We acknowledge that we lack quality, long-term, comparative safety data on the use of antipsychotic agents in the pediatric population. Indeed, the lack of such data is a common theme emphasized throughout the relevant published literature.

Unfortunately, long-term, randomized, placebo-controlled drug safety trials are often not feasible, and that is the case here. Among other considerations, it is unethical to require acutely ill patients to be randomized to placebo and be observed for several months or more without effective treatment. Trials that use another active drug as the comparator instead of placebo might be conducted, but the results of such trials would be difficult to interpret because the absolute risk attributable to the other active drug may not be known or evaluable. Likewise, simply following patients receiving these drugs for a long time with no control group would produce data that would be highly challenging to interpret because it would be unknown whether any observed differences should be attributed to the drug, passage of time, or intercurrent factors. Finally, retention of patients in long-term studies can be difficult, and if a large number of patients drop out over the course of a study, its conclusions may be substantially weakened. For these reasons, assessment of the effects of long-term drug exposure primarily relies on animal data,[7] together with any

[6] Our literature search set out to identify any published adequate (placebo or active-controlled) trials in children or adolescents that provided data with respect to preselected adverse events associated with the use of the new generation antipsychotic drugs (i.e., risperidone, paliperidone, aripiprazole, olanzapine, and quetiapine). These drugs were selected because they have approved pediatric indications. Our search focused on long-term safety data referencing those adverse events we believed to be most important in the pediatric population: hyperprolactinemia, weight gain, hyperlipidemia, extrapyramidal symptoms, and tardive dyskinesia. The PubMed, Embase, and EBSCO Host were among the databases we used.

[7] In fact, before conducting studies in children, juvenile toxicity studies are conducted in young rats,

other relevant long-term safety information available to the Agency.

Thus, we acknowledge that not all adverse reactions associated with the long-term use of these drugs in pediatric patients are detected by clinical investigations or postmarketing surveillance. These include effects on measures such as growth and sexual maturation. We have no comparative data for known adverse events such as gynecomastia.

However, the lack of quality, long-term clinical safety information of the type discussed above is not an appropriate reason to revoke the pediatric indications of Risperdal and Invega when weighed against the potential therapeutic benefit derived from the use of these drugs.

Clinical efficacy of Risperdal and Invega in their approved pediatric indications was demonstrated prior to approval, and numerous pediatric patients have benefited from these drugs despite their known risks. Granting your request that the pediatric indications for Risperdal and Invega be withdrawn unless and until long-term safety is demonstrated would be tantamount to a long-term or permanent withdrawal, thereby removing an important and beneficial therapeutic option for many children and adolescents with these disorders. Withdrawal of these indications would constitute a disservice to the public health.

Accordingly, we do not believe that the standards for withdrawal of approval enumerated in section 505(e) have been met here. Based on reviews of clinical data submitted by the sponsor, published literature, and postmarketing surveillance, there is no evidence that the drug is unsafe, and no evidence that the drug is not shown to be safe, for use under the conditions of use upon the basis of which the applications were approved that would warrant revocation of the pediatric indication of these drugs.

3. *There Is No Basis for Requiring a Boxed Warning Regarding Lack of Long-Term Safety Data Associated With Pediatric Use of Risperdal and Invega*

FDA may require that "[c]ertain contraindications or serious warnings, particularly those that may lead to death or serious injury . . . be presented in a box" on a drug product's labeling (21 CFR 201.57(c)(1)).

As described in the guidance for industry *Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products — Content and Format* (October 2011) (the Boxed Warnings Guidance),[8] a

followed for a period corresponding to human childhood, to detect signals of potential adverse effects with long-term use in developing children. The following areas are assessed in these animal studies: (1) learning, memory, and general behavior (e.g., hyperactivity); (2) histopathology, which entails an examination of various body organs to detect drug-related injury, and (3) reproductive functioning upon reaching young adulthood (including evaluation of mating behavior, fertility, and offspring). See Guidance for Industry: Nonclinical Safety Evaluation of Pediatric Drug Products (February 2006), pp.11-12.

[8] Available at http://www.fda.gov/downloads/Drugs/Guidances/ucm075096.pdf.

boxed warning is ordinarily used to highlight for prescribers one of the following situations:

> There is an adverse reaction so serious in proportion to the potential benefit from the drug (e.g., a fatal, life-threatening, or permanently disabling adverse reaction) that it is essential that it be considered in assessing the risks and benefits of using the drug;
>
> *OR*
>
> There is a serious adverse reaction that can be prevented or reduced in severity by appropriate use of the drug (e.g., patient selection, careful monitoring, avoiding certain concomitant therapy, addition of another drug or managing patients in a specific manner, avoiding use in a specific clinical situation);
>
> *OR*
>
> FDA approved the drug with restrictions to ensure safe use because the drug can be safely used only if distribution or use is restricted (e.g., under 21 CFR 314.520 and 601.42 "Approval with restrictions to assure safe use" or under [21 U.S.C. 355-1(f)(3)] "Risk Evaluation and Mitigation Strategies" Elements to assure safe use).[9]

The Boxed Warnings Guidance also states that, infrequently, a boxed warning can be used in other situations to highlight warning information that is especially important to the prescriber (e.g., reduced effectiveness in certain patient populations). Information included in the WARNINGS AND PRECAUTIONS and CONTRAINDICATIONS sections should therefore be evaluated to determine whether it warrants inclusion in a boxed warning (Boxed Warnings Guidance at 11).

Boxed warnings are most likely to be based on observed serious adverse reactions, but there are instances when a boxed warning based on an anticipated adverse reaction would be appropriate. For example, a contraindication for use during pregnancy based on evidence in humans or animals that drugs in a pharmacologic class pose a serious risk of developmental toxicity during pregnancy would usually be in a boxed warning for all drugs in that class, even those in which an adverse reaction has not been observed. A boxed warning can also be considered for a drug that poses risk-benefit considerations that are unique among drugs in a drug class (Boxed Warnings Guidance at 12).

None of these situations is applicable here, and the concerns you have raised do not otherwise justify a boxed warning. The risks of treatment with these drug products, including the risks with which your petition is principally concerned, are well known.[10]

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[9] Boxed Warnings Guidance at 11.

[10] BJ Sadock, VA Sadock, and P Ruiz (eds.), Kaplan and Sadock's Comprehensive Textbook of Psychiatry, 9th Edition (2009). Williams and Wilkins, pages 3215, 3217-3219.

Gynecomastia is a common clinical manifestation of hyperprolactinemia, regardless of cause,[11] and does not represent a serious adverse event as defined in 21 CFR 312.32(a). We would expect prescribers and patients to discuss these potential risks (together with the potential benefits) before and during treatment, consistent with the applicable standard of care.

Furthermore, we do not think it is appropriate to use a boxed warning to convey, as you request (Petition at 2), a mere *lack* of certain safety data (the long-term comparative safety data discussed in section II.A.2 of this response), particularly where, as we have previously discussed, the risks in question are already well known by prescribers and do not represent serious adverse events.

Finally, other antipsychotic drugs (such as haloperidol, fluphenazine, and perphenazine) have been known for decades to produce hyperprolactinemia as a side effect of their therapeutic action, and this fact is well known within the psychiatric community. The risk of hyperprolactinemia associated with certain antipsychotics has been basic textbook knowledge in psychiatry for many years. For example, there is considerable discussion of the tendency of antipsychotic drugs to elevate prolactin in *Stahl's Essential Psychopharmacology: Neuroscientific Basis and Practical Applications*, (4th edition, published by Cambridge University Press (2013)).[12] This is one of the standard textbooks in the field of psychiatric drug therapy.

Accordingly, your petition does not present any data, nor does the Agency possess any data, that would lead us to conclude that a boxed warning regarding the risk of gynecomastia or, more generally, hyperprolactinemia, is appropriate for the labeling of Risperdal or Invega. For these reasons, we deny your requests to require a boxed warning for Risperdal and all generic versions of risperidone.

B. Labeling Adequacy

Although your petition includes an extensive discussion of the current labeling of Risperdal and Invega, you do not make specific labeling requests other than the request, addressed above, that FDA require a new boxed warning for Risperdal and all generic versions of risperidone. We therefore do not respond to your specific contentions regarding the current labeling of these products. As is the case with all drugs regulated by the Agency, labeling is assessed as appropriate to ensure that it reflects all relevant safety information and labeling updates are sought and implemented as necessary.

[11] Id. at page 3218.

[12] See Page 336.

C. The 2008 Advisory Committee Meeting

Your petition (Petition at 9-13) references the FDA Pediatric Advisory Committee Meeting that was held on November 18, 2008,[13] and asserts that several follow-up actions/recommendations have not been undertaken, including:

1. additional follow-up regarding on-label and off-label product use of this class of drug products, with specific attention to age and indication for which the product is being used;

2. additional follow-up regarding metabolic syndrome, growth, sexual maturation, and hyperprolactinemia;

3. further studies on long-term effects in the pediatric population of this class of products;

4. additional follow-up on extrapyramidal side effects in the pediatric population; and

5. additional evaluation of this class of antipsychotic medications and concomitant drug use.

You do not explain how the 2008 Advisory Committee Meeting supports the specific requests made in your petition – in particular, that FDA revoke the pediatric indication for Risperdal, for all generic versions of risperidone, and for Invega (paliperidone), unless and until the long-term safety of these drug products can be demonstrated; or, in the alternative, that FDA require a new boxed warning for Risperdal and all generic versions of risperidone that would warn of what you characterize as a lack of sufficient safety data. Moreover, we disagree with your contentions regarding asserted Agency inaction following the Advisory Committee meeting. The Agency has been actively engaged in the issues addressed at the 2008 Advisory Committee meeting and has followed up on the Advisory Committee's recommendations as appropriate and necessary.

D. Request for FDA to Direct J&J to Consent to Release Confidentiality/Protective Orders

You request that FDA direct J&J to release your firm from "any and all standing Confidentiality/Protective Orders" so that you can present to the FDA the "internal documents and data," as well as an expert analysis thereof, which you believe support your requested actions (Petition at 2). In the alternative, you ask that FDA request that J&J submit "all internal documents, including e-mails and correspondence, as well as documents and testimony from the Risperdal litigation" (Petition at 1, footnote 2). You further ask that should FDA make such a request to J&J, any documents produced by J&J

[13] Transcript available at http://www.fda.gov/ohrms/dockets/ac/08/minutes/2008-4399m1.pdf.

should either be made available for public review and comment or made available to you for "in camera review" (Petition at 2, footnote 2). We refer collectively to these alternative requests as the "Additional Information Request."

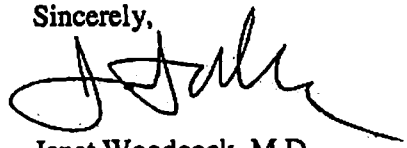
In response to the Additional Information Request, we asked J&J to provide any data in its possession relevant to the use of risperidone or paliperidone in children and adolescents that J&J had not previously provided to the Agency. We referenced your petition and your amended petition in our letter and included those documents as attachments to our letter. J&J provided certain information in response to our request, which we considered along with all other relevant information available to us in addressing your Petition. We decline to take any of the other specific actions you requested in connection with the Additional Information Request.[14]

Accordingly, the Additional Information Request is granted in part and denied in part.

III. CONCLUSION

For the reasons stated above, your requests are denied, except for the Additional Information Request, which is granted in part and denied in part.

Sincerely,



Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

[14] Given our disposition of the Additional Information Request, we need not reach, and make no comment on, our legal authority to take any of the specific actions you request in connection with the Additional Information Request.

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	CV 11-08334 GAF (FMOx)	Date	March 16, 2012
Title	Physicians for Integrity in Medical Research, Inc. v. Commissioner		

Present: The Honorable	**GARY ALLEN FEESS**	
Renee Fisher	None	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:	
None	None	

Proceedings: **(In Chambers)**

ORDER RE: MOTION TO DISMISS AMENDED COMPLAINT

I.
INTRODUCTION & BACKGROUND

Plaintiff Physicians for Integrity in Medical Research, Inc. ("PIMR") brings this action against the Commissioner of the Food and Drug Administration ("FDA") in connection with the Agency's approval of a new treatment for bronchial asthma. (Docket No. 8, First Am. Compl. ("FAC").) PIMR is a non-profit, public benefit organization aimed at "stress[ing] integrity and honesty in medical research, to educate the public and the government about the bias in medical research and to protect the interests of patients." (Id. ¶ 3.) Steve Gupta ("Gupta") is the director and president of PIMR, as well as the attorney for the organization in this lawsuit. (Id. ¶ 4). In July 2010, Gupta filed a citizen's petition with the FDA, asking the Agency to revoke its approval of the Alair Bronchial Thermoplasty System, a new medical device used for the treatment of bronchial asthma. (Id. ¶ 6.) Gupta's petition outlined various reasons why he believed Alair was neither safe nor effective. (Id.) Based on additional clinical data, Gupta submitted supplemental information to the FDA in December 2010 and April 2011. (Id. ¶ 8.) Following's PIMR's initiation of this suit, the FDA rejected the petition on December 2, 2011. (Id. ¶ 10; Docket No. 8, Ex. 5 [FDA Denial Letter].)

Plaintiff details a number of problems with the device, alleging that, due to insufficient study of the procedure, "[t]here is no way for the patients to know if the surgery helps or if the benefits are from the placebo effect," and that the procedure is excessively expensive and "a waste of precious funds." (Id. ¶¶ 11–26.) Plaintiff seeks de novo review and revocation of the

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UNITED STATES DISTRICT COURT
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FDA's approval of Alair, a declaration that Alair is neither safe nor effective, and attorney's fees and costs. (Id. ¶ 28.)

The Commissioner now moves to dismiss the complaint pursuant to Federal Rule of Civil Procedure 12(b)(1), contending that Plaintiff lacks standing because he has alleged no injury that would satisfy Article III's standing requirements. (Docket No. 5.) In the alternative, the Commissioner asks the Court to strike certain elements contained in PIMR's prayer for relief. For the reasons set forth below, the Court concludes that the motion to dismiss should be **GRANTED**.

II.
DISCUSSION

A. LEGAL STANDARDS GOVERNING STANDING

Lack of subject matter jurisdiction is grounds for dismissal under Federal Rule of Civil Procedure 12(b)(1). See Fed. R. Civ. P. 12(b)(1). Federal courts must determine issues of subject matter jurisdiction before even considering the merits of a case. See Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 94 (1998). Where a plaintiff lacks standing, a federal court lacks subject matter jurisdiction over the suit. Cetacean Cmty. v. Bush, 386 F.3d 1169, 1174 (9th Cir. 2004). A party seeking to invoke this Court's limited jurisdiction bears the burden of establishing that it has standing. Lopez v. Candaele, 630 F.3d 775, 784–785 (9th Cir. 2010).

The constitutional standing doctrine requires that those seeking to invoke federal jurisdiction "must satisfy the threshold requirement imposed by Article III of the Constitution by alleging an actual case or controversy." City of Los Angeles v. Lyons, 461 U.S. 95, 101 (1983). The standing inquiry asks "whether the litigant is entitled to have the court decide the merits of the dispute or of particular issues," and "involves both constitutional limitations on federal-court jurisdiction and prudential limitations on its exercise." Warth v. Seldin, 422 U.S. 490, 498 (1975). To satisfy Article III's standing requirements, the plaintiff must show that "'[1] it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; [2] the injury is fairly traceable to the challenged action of the defendant; and [3] it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.'" Maya v. Centex Corp., 658 F.3d 1060, 1067 (9th Cir. 2011) (quoting Friends of the Earth v. Laidlaw Envtl. Servs., Inc., 528 U.S. 167, 180–81 (2000) (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992)).

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An organization may have standing either [1] "in its own right to seek judicial relief from injury to itself and to vindicate whatever rights and immunities the association itself may enjoy"; or [2] as a representative of a member who would otherwise have standing. Warth, 422 U.S. at 511 (citations omitted). "An association has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." Friends of the Earth, Inc. v. Laidlaw Envtl Servs., Inc., 528 U.S. 167, 181 (2000) (citations omitted).

The Ninth Circuit has held that an organization has "'direct standing to sue [when] it show[s] a drain on its resources from both a diversion of its resources and frustration of its mission.'" Fair Hous. Council of San Fernando Valley v. Roommate.com, LLC, 666 F.3d 1216, 1219 (9th Cir. 2012) (quoting Fair Hous. of Marin v. Combs, 285 F.3d 899, 905 (9th Cir. 2002)). However, "standing must be established independent of the lawsuit filed by the plaintiff." Id. (internal citations and quotation marks omitted). An organization "cannot manufacture [an] injury by incurring litigation costs or simply choosing to spend money fixing a problem that otherwise would not affect the organization at all." Id. (internal citations and quotation marks omitted).

B. PIMR'S STANDING TO ASSERT CLAIMS AGAINST THE FDA

Defendant contends that "PIMR lacks standing because it has not alleged, and cannot establish, that any member of the organization was injured by [the] FDA's decision not to revoke approval of the Alair device." (Mem. at 4.) Plaintiff asserts that the organization has standing because the FDA rejected Gupta's citizen's petition filed under 21 C.F.R. § 10.30(b). (FAC ¶ 4.) Because Gupta exhausted his administrative remedies, PIMR claims that it has standing under the Administrative Procedures Act ("APA"), 5 U.S.C. § 500–596. (Id.) PIMR further alleges that Gupta requested that it file this lawsuit, and that Gupta's participation is not required in the resolution of the matter. (Id.)

21 C.F.R. § 10.30 allows a person to request that the Commissioner of the FDA "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.30(b). Although FDA regulations state that "[a]n interested person is affected by, and thus has standing to obtain judicial review of final agency action," that regulation does not and cannot confer Article III standing. See 21 C.F.R. § 10.45(d)(1)(ii); Rivas v. Rail Delivery Service, Inc., 423 F.3d 1079, 1083 (9th Cir. 2005) ("A federal statute, however, cannot confer standing on plaintiffs who do not meet Article III requirements."); Klamath Water Users Ass'n v. F.E.R.C., 534 F.3d 735, 738 (D.C. Cir. 2008)

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

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Title	Physicians for Integrity in Medical Research, Inc. v. Commissioner		

("Petitioners do not have a right to seek court review of administrative proceedings merely because they participated in them. Unlike an agency, [a federal court's] authority to hear a case is limited by the standing requirements of the United States Constitution.")

Nor does Plaintiff's FAC independently meet Article III's standing requirements. The FAC has not alleged that PIMR has any members, nor that Gupta is a member, nor that Gupta or any of the organization's members suffered an injury in fact. Plaintiff's contention in opposition that PIMR's director, namely Steve Gupta, is a "member-equivalent" does not cure these deficiencies. See Fund Democracy, LLC v. S.E.C., 278 F.3d 21, 25 (D.C. Cir. 2002) ("It does not appear that Fund Democracy actually has any members. In any event, Fund Democracy has not shown that any of the individual mutual fund investors it claims as 'members' have standing to sue in their own right.") Although Plaintiff alleges additional facts in the opposition, the Court cannot consider, on a motion to dismiss, facts alleged solely in the parties' briefing. Moreover, to the extent that Plaintiff implies that the organization's injury stems solely from the FDA's denial of Gupta's citizen's petition, these allegations do not, as noted above, meet the injury-in-fact requirement for purposes of Article III standing. Standing must be established independent of the Agency's administrative denial.

With respect to direct organizational standing, Plaintiff contends in opposition that because "PIMR and its supporting physician members, including Dr. Gupta, are in the business of patient care", any injury to asthmatic patients caused by Alair "will reflect negatively upon the business and professional standing of physicians as [a] whole, and specifically Dr. Gupta," as he is the director of PIMR. (Opp. at 3.) That conclusion is not supported by any facts, and Plaintiff has cited no authority for the proposition that such a broad, non-specific "negative light" injury could ever support Article III standing. Rather, the case law requires either a drain on an organization's resources (other than the resources used to fight the lawsuit in which standing is alleged) or a frustration of its mission. Neither has been, nor is likely that either could be, alleged in this case. In fact, PIMR explicitly states in the complaint that the organization "has no financial interest in the outcome of this case." (FAC ¶ 4.) The entirely speculative prospect that some asthmatic patient might feel negatively about physicians who do not challenge the FDA approval of Alair is insufficient to confer Article III standing on Plaintiff.

Finally, Plaintiff has not alleged that the FDA committed any procedural violation during the consideration of its petition; rather, PIMR seeks de novo review of the merits of the Agency's determination. See Portland Audubon Soc. v. Endangered Species Committee, 984 F.2d 1534, 1537 (9th Cir. 1993) ("The environmental groups have Article III standing if for no other reason than that they allege procedural violations in an agency process in which they

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

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participated.") (citing Lujan, 504 U.S. at 555.)

The Court therefore concludes that, as the complaint is currently pleaded, PIMR lacks standing to bring this action. Accordingly, the motion is **GRANTED** and the complaint is **DISMISSED with leave to amend.**

III.
CONCLUSION

For the reasons set forth above, the motion is **GRANTED**. Failure to file an amended complaint curing the deficiencies the Court has identified by **Thursday, April 5, 2012** will be deemed consent to dismissal of the complaint with prejudice. The hearing currently scheduled on this motion for March 19, 2012 is **VACATED**.

IT IS SO ORDERED.

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	CV 11-08334 GAF (FMOx)	Date	May 23, 2012
Title	Physicians for Integrity in Medical Research, Inc. v. Commissioner		

Present: The Honorable	**GARY ALLEN FEESS**	
Chris Silva for Renee Fisher	None	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:	
None	None	

Proceedings: **(In Chambers)**

ORDER RE: MOTION TO DISMISS AMENDED COMPLAINT

I.
INTRODUCTION & BACKGROUND

Plaintiff Physicians for Integrity in Medical Research, Inc. ("PIMR") seeks to challenge Defendant Commissioner of the Food and Drug Administration's ("FDA") approval of a new treatment for bronchial asthma called the Alair Bronchial Thermoplasty System ("Alair"). (Docket No. 19, Second Am. Compl. ("SAC").) PIMR is a non-profit, public benefit organization aimed at "advocvat[ing] for patients and [the] public in the field of medical research and introduction of new drugs and medical devices." (Id. ¶ 3.) Steve Gupta ("Gupta") is a director and the president of PIMR, as well as the attorney representing the organization in this case. (Id. ¶ 7). In July 2010, Gupta filed a citizen's petition with the FDA, asking the Agency to revoke its approval of Alair. (Id. ¶ 10.) Gupta's petition outlined various reasons why he believed Alair was neither safe nor effective. (Id.) Based on additional clinical data, Gupta submitted supplemental information to the FDA in December 2010 and April 2011. (Id. ¶ 12.) Following's PIMR's initiation of this suit, the FDA sent Gupta a detailed letter explaining its reasons for rejecting the petition. (Id. ¶ 14; Ex. 7 [December 2, 2011 FDA Denial Letter].)

In its complaint, PIMR details a number of problems with the device, alleging that, due to insufficient study of the procedure, "[t]here is no way for the patients to know if the surgery helps or if the benefits are from the placebo effect," and that the procedure is excessively expensive and "a waste of precious funds." (Id. ¶¶ 17–33.) Plaintiff seeks de novo review of the FDA's decision that Alair is safe and effective, or, in the alternative, review under an "arbitrary

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and capricious" standard; a declaration that Alair is neither safe nor effective; a declaration that the FDA's refusal to revoke the approval given to Alair is unlawful; an order revoking Alair's approval; an order directing the FDA to change the labeling of Alair; and fees and costs. (Id. ¶¶ 44–45, at 19–20.)

On Defendant's motion, the Court has previously dismissed PIMR's first amended complaint, finding that the organization and its members lacked standing to bring the action. (Docket No. 17, March 16, 2012 Order.) PIMR subsequently filed a second amended complaint. The Commissioner now again moves to dismiss the complaint pursuant to Federal Rule of Civil Procedure 12(b)(1), contending that PIMR lacks standing because it has alleged no injury that would satisfy Article III's standing requirements. (Docket No. 20.) In the alternative, the Commissioner asks the Court to strike PIMR's request for de novo review of its decision approving Alair. For the reasons set forth below, the Court concludes that the motion to dismiss should be **GRANTED**, and that the complaint should be **DISMISSED with prejudice**.

II.
DISCUSSION

A. LEGAL STANDARDS GOVERNING STANDING

Lack of subject matter jurisdiction is grounds for dismissal under Federal Rule of Civil Procedure 12(b)(1). See Fed. R. Civ. P. 12(b)(1). Federal courts must determine issues of subject matter jurisdiction before even considering the merits of a case. See Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 94 (1998). Where a plaintiff lacks standing, a federal court lacks subject matter jurisdiction over the suit. Cetacean Cmty. v. Bush, 386 F.3d 1169, 1174 (9th Cir. 2004). A party seeking to invoke this Court's limited jurisdiction bears the burden of establishing that it has standing. Lopez v. Candaele, 630 F.3d 775, 784–785 (9th Cir. 2010).

The constitutional standing doctrine requires that those seeking to invoke federal jurisdiction "must satisfy the threshold requirement imposed by Article III of the Constitution by alleging an actual case or controversy." City of Los Angeles v. Lyons, 461 U.S. 95, 101 (1983). The standing inquiry asks "whether the litigant is entitled to have the court decide the merits of the dispute or of particular issues," and "involves both constitutional limitations on federal-court jurisdiction and prudential limitations on its exercise." Warth v. Seldin, 422 U.S. 490, 498 (1975). To satisfy Article III's standing requirements, the plaintiff must show that "'[1] it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; [2] the injury is fairly traceable to the challenged action of the

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defendant; and [3] it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.'" Maya v. Centex Corp., 658 F.3d 1060, 1067 (9th Cir. 2011) (quoting Friends of the Earth v. Laidlaw Envtl. Servs., Inc., 528 U.S. 167, 180–81 (2000) (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992)).

An organization may have standing either [1] "in its own right to seek judicial relief from injury to itself and to vindicate whatever rights and immunities the association itself may enjoy"; or [2] as a representative of a member who would otherwise have standing. Warth, 422 U.S. at 511 (citations omitted). "An association has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." Friends of the Earth, Inc. v. Laidlaw Envtl Servs., Inc., 528 U.S. 167, 181 (2000) (citations omitted).

The Ninth Circuit has held that an organization has "'direct standing to sue [when] it show[s] a drain on its resources from both a diversion of its resources and frustration of its mission.'" Fair Hous. Council of San Fernando Valley v. Roommate.com, LLC, 666 F.3d 1216, 1219 (9th Cir. 2012) (quoting Fair Hous. of Marin v. Combs, 285 F.3d 899, 905 (9th Cir. 2002)). However, "standing must be established independent of the lawsuit filed by the plaintiff." Id. (internal citations and quotation marks omitted). An organization "cannot manufacture [an] injury by incurring litigation costs or simply choosing to spend money fixing a problem that otherwise would not affect the organization at all." Id. (internal citations and quotation marks omitted).

B. PIMR'S STANDING TO ASSERT CLAIMS AGAINST THE FDA

In its March 16, 2012 Order, the Court explained at length why PIMR lacked standing to bring the action:

> Defendant contends that "PIMR lacks standing because it has not alleged, and cannot establish, that any member of the organization was injured by [the] FDA's decision not to revoke approval of the Alair device." (Mem. at 4.) Plaintiff asserts that the organization has standing because the FDA rejected Gupta's citizen's petition filed under 21 C.F.R. § 10.30(b). (FAC ¶ 4.) Because Gupta exhausted his administrative remedies, PIMR claims that it has standing under the Administrative Procedures Act ("APA"), 5 U.S.C. § 500–596. (Id.) PIMR further alleges that Gupta requested that it file this lawsuit, and that Gupta's participation is not required in the resolution of the matter. (Id.)

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21 C.F.R. § 10.30 allows a person to request that the Commissioner of the FDA "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.30(b). Although FDA regulations state that "[a]n interested person is affected by, and thus has standing to obtain judicial review of final agency action," that regulation does not and cannot confer Article III standing. See 21 C.F.R. § 10.45(d)(1)(ii); Rivas v. Rail Delivery Service, Inc., 423 F.3d 1079, 1083 (9th Cir. 2005) ("A federal statute, however, cannot confer standing on plaintiffs who do not meet Article III requirements."); Klamath Water Users Ass'n v. F.E.R.C., 534 F.3d 735, 738 (D.C. Cir. 2008) ("Petitioners do not have a right to seek court review of administrative proceedings merely because they participated in them. Unlike an agency, [a federal court's] authority to hear a case is limited by the standing requirements of the United States Constitution.")

Nor does Plaintiff's FAC independently meet Article III's standing requirements. The FAC has not alleged that PIMR has any members, nor that Gupta is a member, nor that Gupta or any of the organization's members suffered an injury in fact. Plaintiff's contention in opposition that PIMR's director, namely Steve Gupta, is a "member-equivalent" does not cure these deficiencies. See Fund Democracy, LLC v. S.E.C., 278 F.3d 21, 25 (D.C. Cir. 2002) ("It does not appear that Fund Democracy actually has any members. In any event, Fund Democracy has not shown that any of the individual mutual fund investors it claims as 'members' have standing to sue in their own right.") Although Plaintiff alleges additional facts in the opposition, the Court cannot consider, on a motion to dismiss, facts alleged solely in the parties' briefing. Moreover, to the extent that Plaintiff implies that the organization's injury stems solely from the FDA's denial of Gupta's citizen's petition, these allegations do not, as noted above, meet the injury-in-fact requirement for purposes of Article III standing. Standing must be established independent of the Agency's administrative denial.

With respect to direct organizational standing, Plaintiff contends in opposition that because "PIMR and its supporting physician members, including Dr. Gupta, are in the business of patient care", any injury to asthmatic patients caused by Alair "will reflect negatively upon the business and professional standing of physicians as [a] whole, and specifically Dr. Gupta," as he is the director of PIMR. (Opp. at 3.) That conclusion is not supported by any facts, and Plaintiff has cited no authority for the proposition that such a broad, non-specific "negative light" injury could ever support Article III standing. Rather, the case law requires either a drain on an organization's resources (other than the resources used to fight the lawsuit in which standing is alleged) or a frustration of its mission. Neither has been, nor is likely that either could be, alleged

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in this case. In fact, PIMR explicitly states in the complaint that the organization "has no financial interest in the outcome of this case." (FAC ¶ 4.) The entirely speculative prospect that some asthmatic patient might feel negatively about physicians who do not challenge the FDA approval of Alair is insufficient to confer Article III standing on Plaintiff.

Finally, Plaintiff has not alleged that the FDA committed any procedural violation during the consideration of its petition; rather, PIMR seeks de novo review of the merits of the Agency's determination. See Portland Audubon Soc. v. Endangered Species Committee, 984 F.2d 1534, 1537 (9th Cir. 1993) ("The environmental groups have Article III standing if for no other reason than that they allege procedural violations in an agency process in which they participated.") (citing Lujan, 504 U.S. at 555.)

The Court therefore concludes that, as the complaint is currently pleaded, PIMR lacks standing to bring this action. Accordingly, the motion is **GRANTED** and the complaint is **DISMISSED with leave to amend.**

(March 16, 2012 Order at 3–5)

PIMR has not cured any of the numerous deficiencies outlined in this Court's March 16 Order. In its SAC, PIMR now alleges that it has standing because Gupta has standing, and because Gupta has requested that PIMR "initiate and continue litigation." (SAC ¶ 6.) PIMR alleges that "the failure of the FDA to revoke the approval of Alair caused hardship and injury to Gupta . . . because he had and has to explain this new surgery to his patients, and why the surgery is not safe or effective", causing him financial loss. (Id. ¶ 5.) Gupta also alleges that he will suffer loss of income because some patients "will opt for this unsafe surgery and will leave him to go to other physicians who are advocating [it]", and that he will also lose credibility with such patients. (Id.)

Although PIMR now alleges that it has members, it has again failed to allege that any of these members, including Gupta, have standing to bring this suit under Article III. See Friends of the Earth, 528 U.S. at 181 ("An association has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right . . . .") As the Court previously held, the entirely speculative prospect that some asthmatic patient might feel negatively about physicians who do not offer Alair or who do not challenge the FDA's approval of Alair is insufficient to confer Article III standing on Plaintiff. Merely being asked about the procedure, or thereafter deciding to spend time talking about it and/or not offer it to

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patients, does not constitute the sort of "concrete and particularized" injury required under standing doctrine. See, e.g., Coalition for Mercury-Free Drugs v. Sebelius, 725 F.Supp.2d 1, 16 (D.D.C. 2010) (finding contention that "medical professional members [will] suffer ongoing harm to their reputation because of the [FDA's] inability to guarantee that drug and biological products that their medical professional members provide are safe" to be conclusory and insufficient to meet the requirement of "concrete facts demonstrating a particularized injury.") That conclusion, reached a mere two months ago with respect to Plaintiff's FAC, is not in any way brought into question by the allegations contained in PIMR's amended complaint.

III.
CONCLUSION

For the reasons set forth above, the motion is **GRANTED** and the complaint is **DISMISSED with prejudice**. The hearing on the motion presently scheduled for June 4, 2012 is **VACATED**.

IT IS SO ORDERED.